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GENERIC NON-INDIGENOUS PEST RISK ASSESSMENT PROCESS
"The Generic Process"

DRAFT

(For Estimating Pest Risk Associated with the Introduction of Non-Indigenous Organisms)

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CONTENTS

ACRONYMS

APHIS	Animal and Plant Health Inspection Service
BATS	Biological Assessment and Taxonomic Support (PPQ)
CRP	Commodity Risk Potential
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
FS	USDA Forest Service
NAPAP	National Acid Precipitation Assessment Program
NEPA	National Environmental Policy Act
NRC	National Research Council
OTA	U.S. Congress Office of Technology Assessment
PPQ	USDA APHIS Plant Protection and Quarantine
PRP	Pest Risk Potential
USDA	United States Department of Agriculture

I. INTRODUCTION, HISTORY, AND PHILOSOPHY

Objective of the Generic Non-Indigenous Pest Risk Assessment Process

The objective of the Generic Non-Indigenous Pest Risk Assessment Process (hereafter referred to as the Generic Process) is to provide a standardized process for estimating the risk of introducing non-indigenous organisms into a new environment.

The Generic Process was developed for the specific needs of the Animal and Plant Health Inspection Service (APHIS) concerning the introduction of exotic organisms. However, this risk assessment process is flexible enough that it can be used by other interested groups (governmental or non-governmental) to evaluate the introduction, or proposed introduction, of non-indigenous organisms.

The Generic Process was developed to evaluate the risk of non-indigenous organisms associated with a specific commodity or pathway; or evaluate specific species of concern such as recently established exotic species or deliberate introductions. The Generic Process provides a framework where scientific information can be organized into a format that is understandable and useful to managers and decision makers.

The Generic Process was designed to be flexible and dynamic enough to accommodate a variety of approaches to pest risk depending on the available resources, accessibility of the biological information, and the state of the art at the time of the assessment. The Generic Process may be used as a purely subjective evaluation or be quantified to the extent possible or necessary depending on the needs of the assessors. Therefore, the process accommodates the full range of the "types" of assessments required by APHIS, from a simple and quick assessment to an assessment requiring extensive research and sophisticated technologies.

The History and Development of the Generic Process

The development of the Generic Process has been synchronous and functionally tied to the development of various ecological risk assessment methodologies and non-indigenous organism issues. Foremost was the National Research Council's workshops and meetings for the development of the "Ecological Paradigm" (NRC, 1993). The Generic Process's basic approach and philosophy borrows heavily from the NRC's project.

Other major projects and reports which have influenced the direction of the Generic Process are: the Environmental Protection Agency's "Ecological Framework" (EPA, 1992a) and associated

documents (EPA, 1992b, 1992c); the United States Congress Office of Technology Assessment's non-indigenous species report (OTA, 1993); the Forest Service's pest risk assessments on exotic timber pests (USDA, FS, 1991, 1992, 1993); and the risk assessment processes being developed for the Aquatic Nuisance Species Task Force (ANSTF, 1992)(Orr, 1993a).

In addition to the above projects and numerous other pertinent work (see reference section), the following quality criteria (modified from Fischoff et al. 1981) were used in designing the Generic Process:

- Comprehensive - The assessment should review the subject in detail and identify sources of uncertainty in data extrapolation and measurement errors. The assessment should evaluate the quality of its own conclusions. The assessment should be flexible to accommodate new information.
- Logically Sound - The risk assessment should be up-to-date and rational, reliable, justifiable, unbiased, and sensitive to different aspects of the problem.
- Practical - A risk assessment should be commensurate with the available resources.
- Conducive to Learning - The risk assessment should have a broad enough scope to have carry-over value for similar assessments.
- Open to Evaluation - The risk assessment should be recorded in sufficient detail and be transparent enough in its approach that it can be reviewed and challenged by qualified independent reviewers.

Philosophical Discussion of the Generic Process

A. What Risk Assessments can do:

The ultimate goal of the Generic Process is to produce quality non-indigenous pest risk assessments on specific exotic organisms or with non-indigenous organisms identified as being associated with specific pathways (i.e. ballast water, aircraft cargo holds, etc.) or non-indigenous organisms associated with the foreign importation of a specific commodity (i.e. logs, fruits, nursery stock, etc.). The assessments should strive for theoretical accuracy while remaining comprehensible and manageable (USDA, 1983); and the scientific data should be collected, organized and recorded in a formal and systematic manner (USDA, 1990).

If the assessment is associated with the importation of a commodity (a commodity is considered a type of pathway in this paper) it should be able to provide a reasonable estimation of the overall risk due to the possibility that multiple pests may be involved. All assessments should communicate effectively the relative amount of uncertainty involved and, if appropriate, provide recommendations for the mitigation measures that reduce the risk.

B. What Risk Assessments cannot do:

Numerous attempts have been made in the past to produce a process that measures the risk of pest introduction associated with importing commodities (McGregor, 1973; USDA, 1978, 1982, 1986 and Kahn, 1989). The goals of some of these processes reflected what was wanted, not what was possible. Goals that <u>cannot</u> be obtained from a risk assessment are:

1. A risk assessment cannot determine the acceptable risk level. What risk, or how much risk, is acceptable depends on how a person, or agency, perceives that risk. Risk levels are value judgements that are characterized by variables beyond the systematic evaluation of information.

2. It is not possible to determine precisely whether, when, or how a particular introduced organism will become established. It is equally impossible to determine what specific impact an introduced organism will have. This has been stressed by ecologists (Crawley, 1987; Kogan, 1990 and Drake, 1993) and by agricultural pest scientists (Catley, 1990; McGregor, 1973; Sailer, 1978; and USDA, 1983). The best that can be achieved is to estimate the likelihood that a pest may be introduced and estimate its potential to do damage under favorable host/environmental conditions.

The ability of an introduced organism to establish involves a mixture of the characteristics of the organism and the environment in which it is being introduced. The level of complexity between the organism and the new environment is such that whether it fails or succeeds will be based on minute idiosyncrasies of the interaction between the organism and environment. These cannot be predicted in advance by general statements based only on the biology of the organism (Kogan, 1990; Crawley, 1987). Examples of such idiosyncrasies abound in the literature on introduced species. A few examples are; parasitic flies affecting success in competition between two ant species (Feener, 1981), plant release of chemicals to attract ectoparasites initiated by oral secretions from caterpillars (Turlings et al 1990), and a change in the behavior of an introduced pest because of a developmental or mutational event (Porter et al 1988).

In addition, even if extensive information exists on an exotic organism, many scientists believe that the ecological dynamics are so turbulent and chaotic that future ecological events cannot be accurately predicted. Robert May (1987), suggests that even relatively simple ecological predictions are so "chaotic" that it is best to rely upon a nonlinear system for predictions. The outcome of which could not be accurately anticipated by the best mathematical logic and epidemiologic investigation.

A number of theoretical ecologists are beginning to subscribe to the theory of Self-Organized Criticality (Soft Chaos Theory), or modifications thereof, to explain the complexity of ecosystem behavior (Bak and Chen, 1991). James Drake (1993) has convincingly demonstrated that the distribution of species (patches) within the ecological landscape, and the previous invasion history of the ecological landscape, influenced the success and degree of environmental impact that an invasion species would have. Drake also showed that several alternative states of equilibrium were possible in a community due to a species invasion despite identical initial conditions.

3. Non-indigenous organisms cannot be reliably ranked based on the likelihood of becoming established or by their potential impact if established. This is an obvious carry over from #2 above.

These statements do not mean that many successful invaders cannot share generalized characteristics that can be utilized in a risk assessment.

C. Reaching a Philosophical Balance Between what Risk Assessment can and cannot do in APHIS:

If we accept that "it is not possible to determine whether a particular introduced organism will become established", and "it is equally impossible to determine what specific impact an introduced organism will have", then we might be asked, "what value is there in doing risk assessments, which consist of assessing the probability of establishment and the consequence of establishment?".

We cannot determine (say positively "yes" or "no") what will happen because we cannot predict the future with certainty. But like other social agencies (insurance companies, hospitals, Food and Drug Administration), we are required to make estimations of the future in order to manage risks.

Some of the information we use in performing a risk assessment is scientifically defensible, some of it is based on experience or anecdote only, and all of it is subject to the filter of perception. However, we can and must provide an estimation based on the best information we have and use that estimation in deciding whether to allow the importation of a commodity or non-indigenous organism and under what conditions.

The assessment must demonstrate risk in order to initiate regulatory action. In legal terms, we must make estimations of risk in order to restrict or prohibit high risk pathways, with the goal of preventing the introduction of exotic pests., However, again from a regulatory standpoint, we must start with a positive

premise; that everything is risk-neutral until we can determine that it is not.

We must demonstrate that there is a risk (not that there is <u>no</u> risk), before we restrict or prohibit anything. Also, it is usually not practical to try and prove a negative. "Pest risk" has historically been interpreted to mean "a significant degree of pest risk" since there is at least minimal pest risk associated with the movement of any material, and there is no evidence to indicate that government intends to halt all international trade.

D. Managing Uncertainty:

If all was certain, there would not be a need for risk assessment. Uncertainty, as it relates to the individual pest risk assessments, can be divided into three distinct types:

a) uncertainty of the process -- (methodology)
b) uncertainty of the assessor(s) -- (human error)
c) uncertainty of the organism -- (biological unknowns)

Each one of these presents its own set of problems. All three uncertainty types will continue to exist regardless of future developments. The goal is to succeed in reducing the uncertainty in each of these groups as much as possible.

The "uncertainty of the process" requires that the risk methodologies involved with the generic process never become static or routine but continue to be modified when procedural errors are detected and/or new risk methodologies are developed.

"Uncertainty of the assessor(s)" is best handled by having the most qualified and conscientious persons available conduct the assessments. The quality of the risk analysis will, to some extent, always reflect the quality of the individual assessor(s).

The "uncertainty of the organism" is the most difficult to respond to. Indeed, it is the biological uncertainty more than anything else that initiated the need for developing a non-indigenous pest risk process. Common sense dictates that the caliber of a risk assessment is correlated with the quality of data available on the organism. Those organisms for which copious amounts of high quality research have been conducted, are the most easily assessed. Conversely, an organism for which very little is known, cannot be easily assessed.

A healthy concern over a high degree of biological uncertainty should not be elevated to "paranoia". Nature does not conspire against us! A high degree of biological uncertainty, in itself, does not demonstrate a significant degree of risk and therefore should not justify a more restrictive position.

However, those organisms which demonstrate a high degree of biological uncertainty do represent a real risk. The risk of importing a damaging exotic pest (for which little information is known) is probably small for any single assessment but the risk becomes much higher when one considers the vast numbers of these organisms that must be considered. It is not possible to identify which of the "unknowns" will create problems -- only assume that some will. Demonstrating that a pathway has a "heavy" concentration of exotic pests for which little information is present may, in some cases (based on the "type" of pathway and the "type" of organisms), warrant regulatory concern. However, great care should be taken by the assessor(s) to explain why a particular non-indigenous organism load demonstrates a significant risk.

This need to balance "demonstrated risks" against "biological uncertainty" can lead assessors to concentrate more on the uncertainty than on known facts. This is self-destructive since to prohibit or restrict a pathway or specific exotic organism, the reasons or logic should be clearly described.

When evaluating a commodity, conducting a few individual pest risk assessments on those organisms for which information is available will be much more productive than spending time attempting to assess many organisms for which little or nothing is known. Risk assessments should, whenever possible, concentrate on demonstrated risk. Applying mitigating measures based on well documented individual non-indigenous pests will frequently result in a degree of mitigation against other organisms demonstrating high biological uncertainty which might be utilizing the same pathway.

E. Policy-Relevant versus Policy-Driven Assessments and other Warnings:

When conducting risk assessments for regulatory purposes, the most serious obstacles to overcome are the forces of historical precedence and the limitations presented by legal parameters, operational procedures, and political pressure. In order to focus the assessment as much as possible on pest risk, all assessments need to be completed in an atmosphere as free of regulatory and political influences as possible.

The following quote is taken from the NRC's 1983 Red Book on "Risk Assessment in the Federal Government: Managing the Process":

> "We recommend that regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies".

This can be translated to mean that risk assessments should not be *policy-driven*. However, the Red Book then proceeded with a caveat:

"The importance of distinguishing between risk assessment and risk management does not imply that they should be isolated from each other; in practice they interact, and communication in both directions is desirable and should not be disrupted".

This can be translated to mean that the risk assessment, even though it cannot be policy-driven, must be *policy-relevant*. These truths continue to be valid (NRC, 1993).

One of the most glaring examples of an assessment not being policy-relevant was the National Acid Precipitation Assessment Program (NAPAP) as reported by *Science* in the News & Comment Section of their March 15, 1991 issue (Roberts, 1991). Over 2000 scientists were involved over the span of a decade and ½ billion plus dollars was spent on producing a massive risk assessment. However, it was never used in making the policy decision on acid rain because;

"NAPAP became obsessed by the need to have the best science, but the best science and the best models aren't always the best way to get answers to the things that matter most for policy"

"...instead of asking, What do we really need to know to make the wisdom-type calls Congress will be called on to answer over the next 10 years?, NAPAP managers asked, What are the intriguing and seminal scientific questions we can answer in 10 years".

The balance to keep an assessment policy relevant without having the agency's forces direct the outcome of an assessment will always be a challenge to the assessors.

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WARNING 1. Specific or detailed Generic Processes should <u>not</u> be incorporated into regulations (into law) because the assessor will always need the freedom to modify/update the process to fit a particular organism or new risk approach. The processes should be adopted as guidelines or protocols which are not rigidly structured by law.

If it is a legal requirement that "something" be placed into the regulatory language (into law) to ensure that decision making is not arbitrary, then great care should be taken to describe the process in general so as not to force assessors into an inflexible risk assessment process.

WARNING 2. Quantitative risk assessments can provide valuable insight and understanding, however such assessments can never capture all the variables that are important to a regulatory agency. Quantitative risk assessments, when associated with regulatory decisions, should always be buffered with careful human judgment (Morgan, 1981).

WARNING 3. "A third concern involves the inclination of many agencies to produce a single, definitive, analytical tool for dealing with their problems. This shying away from multiple approaches is unfortunate, since much can often be learned by studying and comparing the results of alternative formulations" (Morgan, 1981).

WARNING 4. "... quantitative risk-assessment tools may become a substitute for science. After all, it is generally much cheaper and easier to ask 8 or 10 experts what they believe the value of some variable is than to mount an experimental program to measure it. The results of most quantitative risk assessments look pretty technical, so it is sometimes easy to forget that the technical understanding they are based on is often quite incomplete" (Morgan, 1981).

WARNING 5. "Experts' judgments appear to be prone to many of the same biases as those of the general public, particularly when experts are forced to go beyond the limits of available data and rely on intuition" --- "Strong initial views are resistant to change because they influence the way that subsequent information is interpreted. New evidence appears reliable and informative if it is consistent with one's initial beliefs; contrary evidence tends to be dismissed as unreliable, erroneous, or unrepresentative" --- "Douglas and Wildavsky [1982] assert that people, acting within social groups, downplay certain risks and emphasize others as a means of maintaining and controlling the group" --- "Whereas ... risk debates are not merely about risk statistics, some sociological and anthropological research implies that some of these debates may not even be about risk. Risk concerns may be a surrogate for other social or ideological concerns. When this is the case, communication about risk is simply irrelevant to the discussion" (Slovic, 1987).

WARNING 6. "Basically, if a law [method or process] has many adjustable parameters, then it will be significantly preferred to the simpler law [method or process] only if its predictions are considerably more accurate." (Jefferys & Berger, 1992).

II. THE GENERIC PROCESS FOR CONDUCTING COMMODITY/PATHWAY ANALYSES AND ASSOCIATED PEST RISK ASSESSMENTS

The following details of the Generic Process focus on evaluating the risk of non-indigenous organisms associated with a specific importation of a foreign commodity or some other identified pathway (hereafter referred to as a pathway analysis). Figure 1, on page 11, outlines the flow of a pathway analysis, dividing the process into initiation, risk assessment, and risk management. Specific organisms needing evaluation which are not tied to a pathway assessment would proceed directly to the "*Individual Pest Risk Assessments*" box in Figure 1 (page 11) and the "*Individual Pest Risk Assessments*" section starting on page 13.

The Generic Process is concerned with the initiation and risk assessment of a pathway. The role of risk management is not specifically addressed in the Generic Process. However, information obtained during the risk assessment should be included if it would help risk managers in making their decision (see discussion under Policy-Relevant versus Policy-Driven Assessments and other Warnings, page 6).

The initiation starts either with the request for opening a new pathway (i.e. importing a commodity) which might harbor exotic organisms or the identification of an existing pathway which may be of significant risk. All pathways showing a potential for exotic organism introduction should receive some degree of risk screening. Those pathways that show a high potential for introducing exotic pest organisms should trigger an in depth risk analyses.

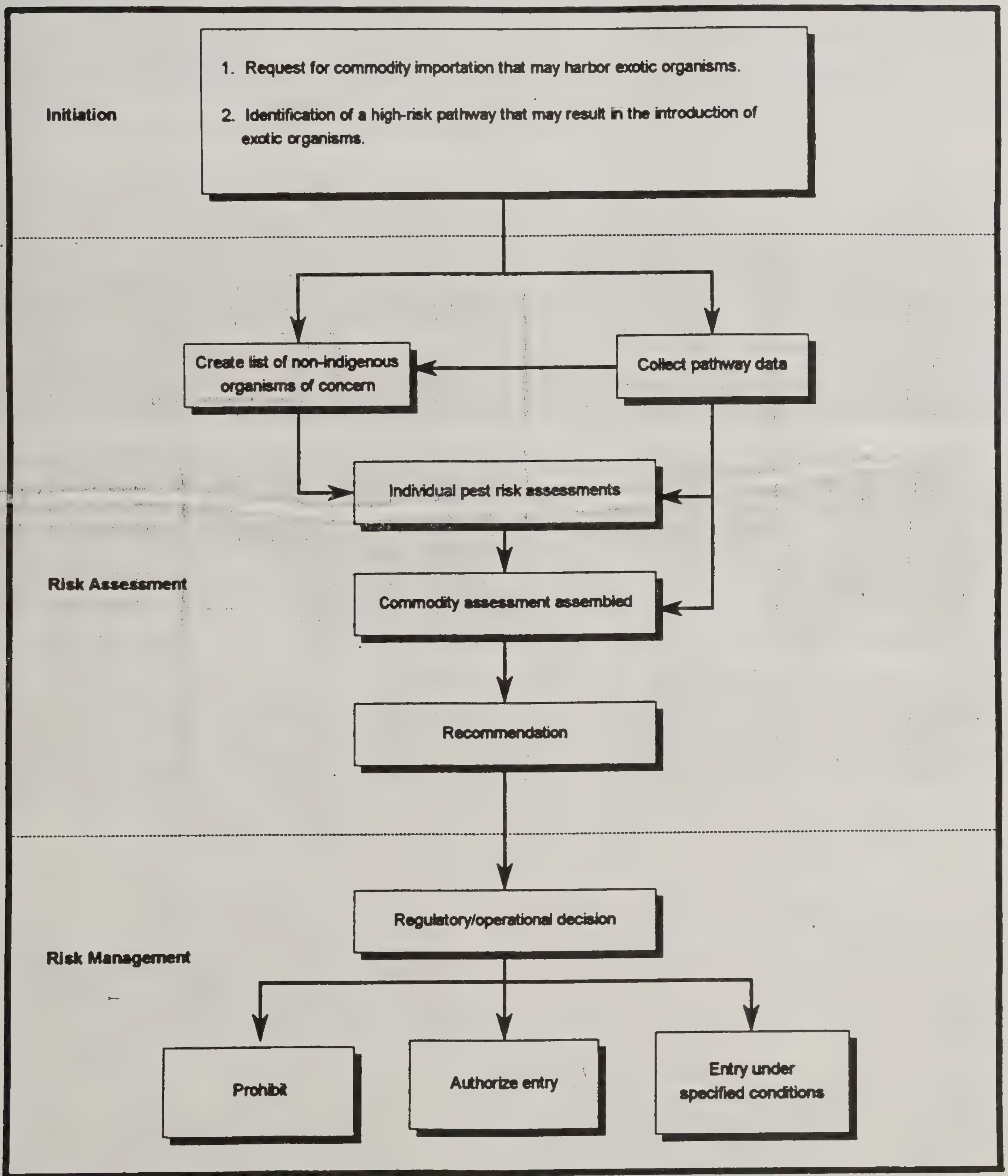
Collecting Pathway Data

Specific information concerning the pathway must be collected. If the pathway is regulated under a permit system, then applicants might be held responsible for providing pertinent data concerning the pathway. This information, coupled with additional data (if necessary), would fulfill the "Collect Pathway Data" element in Figure 1, page 11.

Specific information needed on the pathway will vary depending upon the "type" of pathway (i.e. propagative material, fruit or vegetable importation, aquaculture importation, biocontrol introduction, etc.). The following generalized list of information has been found useful in assessing plant commodities and would have carryover value in evaluating other pathways.

1) Determine exact origin(s) of commodity.
2) Determine volume of commodity to be imported.
3) Determine distribution (time of importation, transit routes, and destination) of commodity after importation.
4) Determine intended use or disposition of commodity (i.e. propagation, food, lumber).
5) Determine method and history of preparing the commodity for importation.
6) Review history of past experiences and previous risk assessments (including foreign countries) on commodity and related commodities from the same origin.
7) Review past and present regulations (including foreign countries) concerning the imported commodity.

Figure 1. Pathway Analysis: Flowchart showing the Initiation, Risk Assessment and Risk Management for a Pathway.



Creating a List of Non-Indigenous Organisms of Concern

The next element in figure 1 (page 11) is "Create List of Non-Indigenous Organisms of Concern". The following generalized process has been used for assessing plant commodity importations for APHIS but would have carryover value for other pathway evaluations.

1) Determine what pests or potential pests are associated with the commodity and are found in the producing region.

2) Determine which of these pests qualify for further evaluation using the table below.

Category	Pest Characteristics	List
1a	species non-indigenous not present in country (United States)	yes
1b	species non-indigenous, in country and capable of further expansion	yes
1c	species non-indigenous, in country and reached probable limits of range, but genetically different enough to warrant concern and/or able to vector another non-indigenous pest	yes
1d	species non-indigenous, in country and reached probable limits of range and not exhibiting any of the other characteristics of 1c	no
2a	species indigenous, but genetically different enough to warrant concern and/or able to vector another non-indigenous pest, and/or capable of further expansion	yes
2b	species indigenous and not exhibiting any of the characteristics of 2a	no

3) Produce a list of the organisms of concern from (step 2) categories 1a, 1b, 1c, and 2a. Taxonomic confusion or uncertainty should also be noted on the list.

4) Conduct Pest Risk Assessments from the list of organisms developed in step 3.

Based on the number of organisms identified and the available resources, it may be necessary to further reduce the number of organisms on the list before conducting the individual pest risk assessments. This can be done using a number of different approaches. Different approaches can be found in each of the three log commodity risk assessments (USDA, Forest Service, 1991, 1992, 1993). Also, the Enhanced Hazard Identification Process (Orr, 1993) has been shown to be effective in focusing resources on those exotic organisms needing further evaluation.

Individual Pest Risk Assessments

The Individual Pest Risk Assessment element in figure 1 (page 11) is the most important component of the Generic Process used in evaluating and determining the pest risk associated with a commodity or pathway. The Individual Pest Risk Assessment element can also be completely independent of a pathway assessment and stand on its own if a particular non-indigenous organism needs to be evaluated. Figure 2, on page 14, represents the Pest Risk Model which drives the individual Pest Risk Assessment.

The Pest Risk Assessment Model is divided into two major components the "probability of establishment" and the "consequence of establishment". This division reflects how the regulatory agency would evaluate an exotic organism (e.g. more restrictive measures are used to lower the probability of a particular exotic pest establishing -- if the consequences of its establishment are greater).

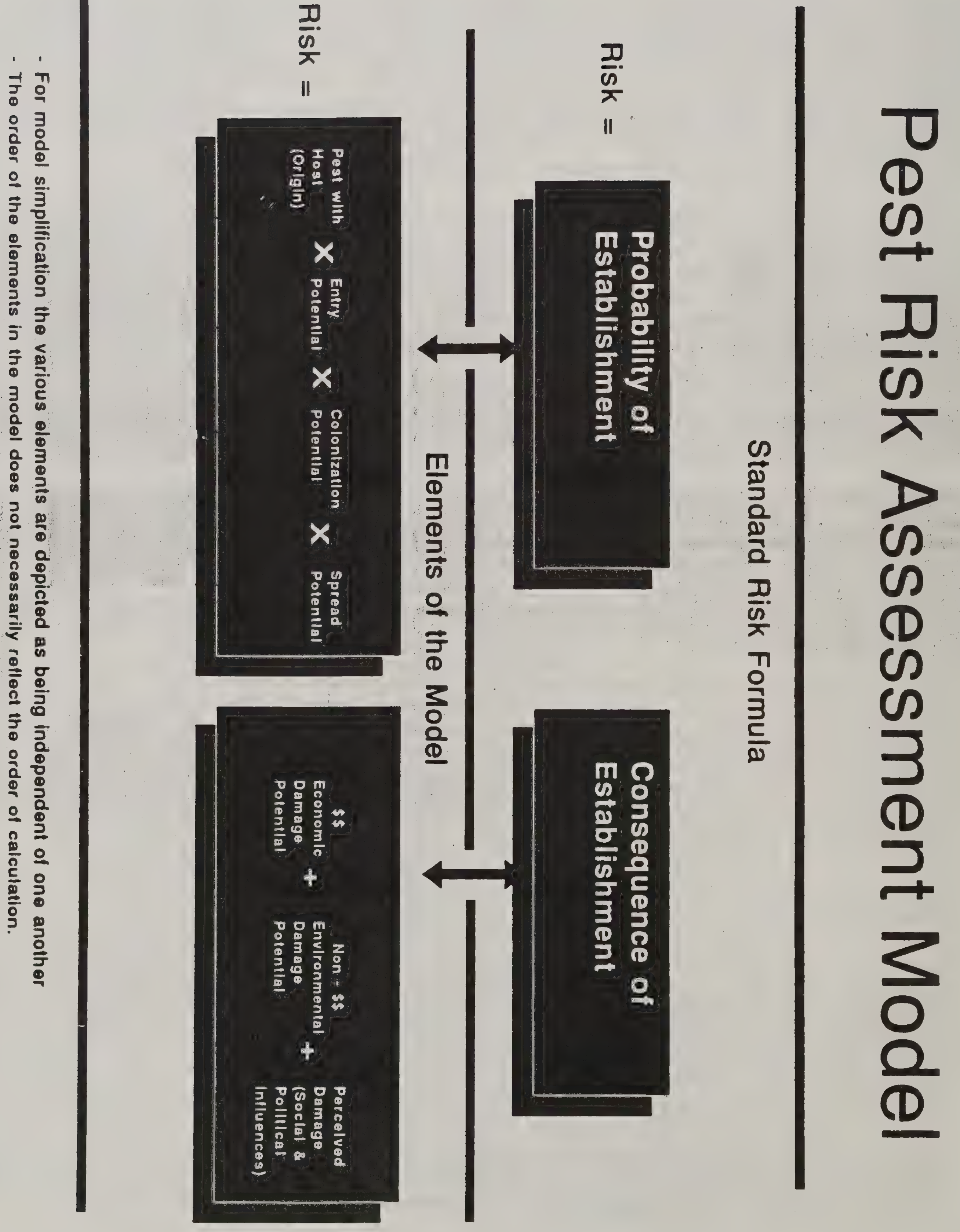
It is important to recognize that the Pest Risk Assessment Model is a working model and represents a simplified version of the real world. In reality the specific elements of the Pest Risk Model are not static or constant, but are truly dynamic showing distinct temporal and spatial relationships. In addition, the elements do not carry equal value in weighing the risk nor are they necessarily independent of each other. The weight of the various elements will never be static because they are strongly dependant upon the exotic organism and its environment at the time of the organism's introduction.

The two major components of the Pest Risk Assessment Model are further divided into 7 basic elements which serve to focus biological information into the assessment. Each of these 7 basic elements are represented on the Risk Assessment Form (Appendix A, page 28) as probability or impact estimates. These may be determined using quantitative or subjective methods. See Appendix B (page 30) for a minimal subjective approach.

The strength of the assessment is that the information gathered by the assessor(s) can be organized under the seven elements. In this way the accumulative information under each element will provide the raw material for making a risk judgement about that element. Whether the methodology used in making the risk judgement for that element is quantitative, qualitative, or a combination of both; the information associated with the element (along with its references) will function as the information source. Placing the information in order of descending risk under each element will further communicate to reviewers the thought process of the assessor(s).

This makes the Generic Process transparent to reviewers and an effective way to identify information gaps. This transparency can also provide a structure for discussion if scientific or technical

Figure 2:


Pest Risk Assessment Model
Standard Risk Formula
Risk =
Probability of Establishment
Consequence of Establishment
Elements of the Model
Risk =
Pest with Host (Origin)
X
Entry Potential
X
Colonization Potential
X
Spread Potential
$$ Economic Damage Potential
+
Non - $$ Environmental Damage Potential
+
Perceived Damage (Social & Political Influences)
- For model simplification the various elements are depicted as being independent of one another
- The order of the elements in the model does not necessarily reflect the order of calculation.

disagreement on an element-rating occurs. For example, if a reviewer disagrees with the rating that the assessor assigns an element the reviewer can point to the information used in determining that specific element-rating and show what information is missing, misleading, or in need of further explanation. Focusing on information to defuse a disagreement will often reduce the danger of emotion or a preconceived outcome from diluting the quality of the element-rating by either the assessors or the reviewers.

The characteristics and explanations of the seven elements of the Pest Risk Assessment Model are as follows:

A. Elements -- Group 1: Assess Probability of Pest Establishment

1. Pest with Host/Pathway (At Origin) -- Estimate probability of the organism being on, with, or in the pathway.

The major characteristic of this element is: Does the organism show a convincing temporal and spatial association with the pathway.

2. Entry Potential -- Estimate probability of the organism surviving in transit.

Some of the characteristics of this element include: the organism's hitchhiking ability in commerce, ability to survive during transit, stage of life cycle during transit, number of individuals expected on associated with the pathway, or whether it is deliberately being introduced for establishment (biocontrol agent or germplasm).

3. Colonization Potential -- Estimate probability of the organism colonizing and maintaining a population where introduced.

Some of the characteristics of this element include: the organism coming in contact with an adequate food resource, encountering appreciable environmental resistance, and ability to reproduce in the new environment.

4. Spread Potential -- Estimate probability of the organism to spread beyond the colonized area.

Some of the characteristics of this element include: ability for natural dispersal, ability to use human activity for dispersal, ability to readily develop races or strains, and the estimated range of probable spread.

B. Elements -- Group II: Assess Consequence of Establishment

5. Economic Damage Potential -- Estimate economic impact if established.

Some of the characteristics of this element include: economic importance of hosts, damage to crop or natural resources, effects to subsidiary industries, exports, control costs, and efficacy.

6. Environmental Damage Potential -- Estimate environmental impact if established.

Some of the characteristics of this element include: ecosystem destabilization, reduction in biodiversity, reduction or elimination of keystone species, reduction or elimination of endangered/threatened species, and effects of control measures.

7. Perceived Damage (Social & Political Influences) -- Estimate impact from social and/or political influences.

Some of the characteristics of this element include: aesthetic damage, consumer concerns, and political repercussions.

Often the assessor feels uncomfortable dealing with the categories of Economic and Perceived Damage. However, his/her input into these categories is often helpful in making regulatory decisions. The assessor should not be expected to reflect, or second guess, what an economist or politician would conclude but rather to present information gathered on the organism that would (or could) have an affect in these areas.

The elements considered under Consequences can also be used to record positive impacts that a non-indigenous organism might have; such as a biocontrol agent, game animal, scientific research, or as a new crop. The elements in the case of deliberate introductions would record information that will be useful in determining the element-rating that would be a balance between the cost, the benefit, and the risk of introducing the exotic organism.

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The Pest Risk Assessment Form (shown in Appendix A, page 28) should be flexible. Each exotic organism is unique. The assessor needs to have the freedom to modify the form to best represent the risk associated with that particular organism. The seven elements need to be retained to calculate the risk but other sections may be added or subtracted without concern. If the assessor feels that information, ideas, or recommendations would be useful, they should be included in the assessment. The assessor can combine "like" organisms into a single assessment if the biology permits (e.g. defoliating Lepidoptera on New Zealand pine, root feeding nematodes of Caribbean sugarcane, tropical aquarium fish destined to temperate North America, etc.).

The number of pest risk assessments to be completed from the list of quarantine pests for a particular pathway depends on several factors. These include the amount of individual organism

information, available resources, and the assessor's judgement concerning whether the completed pest risk assessments effectively represent the pathways' non-indigenous organism risk.

The source of the biological statements and the degree of uncertainty the assessor feels is associated with each rating element, needs to be recorded in the Pest Risk Assessment. The use of the Reference Codes at the end of each statement, coupled with the use of the Uncertainty Codes for each element, fulfills this requirement. Both the Reference Codes and the Uncertainty Codes are described in Appendix A on page 29.

If a federal agency uses the Generic Process for dealing with potential environmental problems much of the information may be relevant to meeting that agency's NEPA requirements. When both NEPA documentation and a risk assessment are warranted, care should be taken to tie the two together so that vital resources are not duplicated. Although a risk assessment is similar to an Environmental Impact Statement (EIS) the risk assessment differs by focusing on the probability of occurrence and the impact of that occurrence, while an EIS generally places its emphasis on who or what will be impacted. Therefore, a risk assessment is more likely to clarify possible outcomes, determine or estimate their probabilities of occurrence, and succeed in recording the degree of uncertainty involved in making the predictions.

Summarizing Pest and Pathway Risk

A value of risk is made at three levels in the Generic Process. The first, is placing a risk value on each of the seven elements within the Pest Risk Assessment (element-rating). The second, is combining the seven risk values into a final Pest Risk Potential (PRP) which represents the overall risk of the organism being assessed. The third, is the combination of the various PRPs into a Commodity/Pathway Risk Potential (CRP) which will represent the combined risk associated with the pathway.

The assigning of either a quantitative or a subjective value to an individual element, and determining how the specific elements in the Model relate to each other, and how the values should be combined, are without doubt the most difficult steps in a pest risk assessment. There is not, and probably never will be, a "correct" formula for completing these steps. Various methodologies such as Geographical Information Systems, Climate and Ecological Models, decision-making software, Expert Systems, and Graphical Displays of Uncertainty all have the potential for increasing the predictive value of one or more elements in the Risk Model. Indeed, risk assessments should never become so static and routine that new methodologies can not be tested and incorporated.

When evaluating new technologies and approaches it is important to keep in mind that the elements of the Pest Risk Model are dynamic, chaotic, and not equal in value. New technologies or approaches which may be appropriate for assessing one organism may be immaterial or even misleading in evaluating another organism. The warnings on pages 7 and 8 should always be kept in mind.

The high, medium, and low approach presented in Appendix B page 30 for calculating and combining the various elements is judgmental. The process in Appendix B is a generic minimum for determining and combining the element values and should not be interpreted as "the best way it could be done".

The strength of the Generic Process is that the biological statements under each of the elements will always provide the raw material for testing various approaches. Therefore, the risk assessments will not need to be re-done to test new methods for calculating or summarizing the PRPs and CRPs.

On risk issues of high visibility, it is important that outside examination of the draft assessment be completed by pertinent reviewers not associated with the outcome of the assessment. This is particularly necessary when the risk assessments are produced by the same agency, professional society, or organization that is responsible for the management of that risk.

Components of the Final Commodity/Pathway Assessment

A completed Commodity/Pathway Assessment should contain the following.

- Tracking/Information Form or Section

Documents the analysis process and records information about why the assessment was done, who the assessment was done for, and information which might not be found in the assessment itself but would be useful background information for future reviewers. It also would contain information that would be helpful in determining (at a later date) the depth of the review, which resources were used and which methodologies were tried but not used in the final assessment. The main function of this form or section would be to provide additional transparency to the assessment and to provide a historical record for future reviewers.

- Commodity/Pathway Information Form or Section

- A complete list of the organisms of concern

- The individual Pest Risk Assessments

- Response to specific questions requested by risk managers

- Summation of the methodology used in determining the PRPs and CRPs

- Summation and responses to outside reviewers

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APPENDIX A:

ASSESSMENT FORM
(With Uncertainty and Reference Codes)

ORGANISM ______________________ **FILE NO.** __________
ANALYST ______________________ **DATE** __________
PATHWAY ______________________ **ORIGIN** __________

I. **SUMMARY OF LIFE CYCLE, DISTRIBUTION, AND NATURAL HISTORY** (include references):

II. **PATHWAY INFORMATION** (include references):

III. **RATING ELEMENTS:** Rate statements as low, medium, or high. Place specific biological information in descending order of risk with reference(s) under each element that relates to your estimation of probability or impact. Use the Reference Codes at the end of the biological statement where appropriate and the Uncertainty Codes after each element rating.

==========================

PROBABILITY OF ESTABLISHMENT

____ Estimate probability of the exotic organism being on, with, or in the pathway.

____ Estimate probability of the organism surviving in transit.

____ Estimate probability of the organism successfully colonizing and maintaining a population where introduced:

____ Estimate probability of the organism to spread beyond the colonized area.

==========================

CONSEQUENCE OF ESTABLISHMENT

____ Estimate economic impact if established.

____ Estimate environmental impact if established.

____ Estimate impact from social and/or political influences.

IV. ADDITIONAL FACTORS AND NOTES:

V. **Pest Risk Potential** __________

VI. MAJOR REFERENCES

****

REFERENCE CODES TO ANSWERED QUESTIONS

Reference Code	Reference Type
(G)	General Knowledge, no specific source
(J)	Judgmental Evaluation
(E)	Extrapolation; information specific to pest not available; however information available on similar organisms applied
(Author, Year)	Literature Cited

UNCERTAINTY CODES TO INDIVIDUAL ELEMENTS

Uncertainty Code	Symbol	Description
Very Certain	VC	As certain as I am going to get
Reasonably Certain	RC	Reasonably certain
Moderately Certain	MC	More certain than not
Reasonably Uncertain	RU	Reasonably uncertain
Very Uncertain	VU	A guess

APPENDIX B: JUDGMENTAL CALCULATION OF PEST RISK AND COMMODITY RISK

Step 1. Calculating the elements in the Risk Assessment

The blank spaces located next to the individual elements of the risk assessment form (Appendix A) can be rated using high, medium, or low. The detailed biological statements under each element will drive the judgmental process. Choosing a high, medium, or low rating, while admittedly subjective, forces the assessor to use the biological statements as the bases for his/her decision. Thus, the process remains transparent for peer review.

The high, medium, and low ratings cannot be defined or measured -- they have to remain judgmental. This is because the value of the elements contained under "probability of establishment" are not independent of the rating of the "consequences of establishment". <u>It is important to understand that the strength of the Generic Process is not in the element-rating but in the detailed biological statements that motivates them</u>.

Step 2. Calculating the Pest Risk Potential

The Pest Risk Potential and the Commodity Risk Potential ratings of high, medium, and low are defined at the end of Appendix B page 33.

The following 3 steps must be completed in order to calculate the Pest Risk Potential.

Step 2a. Determine Probability of Establishment

Probability of Establishment	=	[Pest with Host]	[Entry Potential]	[Colonization Potential]	[Spread Potential]

The element with the lowest risk rating acquires the total rating of Probability of Establishment (example: a high, low, medium, and medium estimate for the above elements would result in a low rating).

This approach is very conservative. In reality (assuming the individual elements are independent of each other) when combining a series of probabilities (such as medium - medium - medium) the probability will become much lower than the individual element ratings. However, the degree of biological uncertainty within the various elements is so high that a conservative approach is well justified.

Step 2b. Determine Consequence of Establishment

Consequence of Establishment = $\boxed{\text{Economic}}$ $\boxed{\text{Environmental}}$ $\boxed{\text{Perceived}}$

Consequence of Establishment =

H	L,M,H	L,M,H	= H
L,M,H	H	L,M,H	= H
M	M	L,M,H	= M
M	L	L,M,H	= M
L	M	L,M,H	= M
L	L	M,H	= M
L	L	L	= L

Note that the three elements that make up the Consequence of Establishment are not treated as equal. The Consequence of Establishment receives the highest rating given either the Economic or Environmental element. The Perceived element does not provide input except when Economic and Environmental ratings are low (see next to the last column on the above table).

Step 2c. Determine Pest Risk Potential (PRP)

PEST RISK = [PROBABILITY OF ESTABLISHMENT] [CONSEQUENCE OF ESTABLISHMENT]

PEST RISK =	High Medium Low	High High High	= High = High = Medium
	High Medium Low	Medium Medium Medium	= High = Medium = Medium
	High Medium Low	Low Low Low	= Medium = Medium = Low

Again the approach is conservative. When a borderline case is encountered (lines 2, 4, 6, 8 on the above chart) the higher rating is accepted. The conservative approach is necessary to help counteract the high degree of uncertainty usually associated with biological situations.

Step 3. Determine the Commodity/Pathway Risk Potential (CRP)

PRP		CRP
Rating	Number	Rating
High	1 or more	High
Medium	5 or more	High
Medium	1 to 4	Medium
Low	1 or more	Low

The CRP reflects the highest ranking PRP. The only exception to this is when the number of medium risk organisms reaches a level in which the total risk of the commodity becomes high. The number, 5 or more, used in the above table is arbitrary.

===========

Definition of Ratings used for Pest Risk Potential and Commodity/Pathway Risk Potential:

Low = acceptable risk - organism(s) of little concern (does not justify mitigation or regulation)

Medium = unacceptable risk - organism(s) of moderate concern (either mitigate or regulate)

High = unacceptable risk - organism(s) of major concern (either mitigate or regulate)

The medium and high ratings combined have the same meaning as Kahn's 1989 definition of Quarantine significance: "Determining whether an organism is important enough to the goals, objectives, missions, or responsibilities of a ... governmental agency to justify agency involvement".

A concrete separation between the Medium and High ratings is not provided and does represent an obvious "gray area" of possible overlap. However, since both the High and Medium ratings are normally of regulatory concern, an organism which falls within this gray area will procedurally be handled the same.

APPENDIX C: ELEMENTS OF RISK MANAGEMENT AND OPERATIONAL REQUIREMENTS

A. Elements To Consider In Risk Management:

- Risk Assessments (including uncertainty and quality of data)
- Available Mitigation Safeguards (i.e. permits, fumigation, inspection)
- Resource Limitations
- Public Perceptions/Perceived Damage
- Social and Political consequences
- Benefits must outweigh cost and/or justify the risk

B. When risk management follows a pathway assessment, the following four steps should be accomplished:

- Step 1: Maintain communication and input from stakeholders,
- Step 2: Maintain an open communication with those responsible for conducting the pest risk assessment,
- Step 3: Match the available mitigation options with the identified risks and,
- Step 4: Develop a realistic operational approach that maximizes the balance between protection and resources.

STEP 1: Stakeholder participation should be actively solicited as early as possible. Care should be given to make sure that relevant stakeholders are identified since adding stakeholders late in the assessment or management process can result in revisiting issues already examined and thought to have been brought to closure. All identified stakeholders should be periodically brought up-to-date on relevant issues.

STEP 2: Continuous open communication between the risk managers and the risk assessors is important throughout the writing of the risk assessment. This is necessary to ensure that the assessment will be policy relevant when completed. Risk Managers should be able to provide detailed questions about the issues that they will need to address to the risk assessors <u>before</u> the risk assessment is started. This will allow the assessors to focus the scientific information relevant to the questions (issues) that the risk managers will need to address.

STEP 3: Matching the available mitigation options with the identified risks can sometimes be done by creating a mitigation matrix placing the organisms, or groups of organisms, identified in a specific pathway along one axis and the available mitigation options along the other. Where a specific organism, or group of organisms, meets a specific mitigation process in the matrix, the efficacy for control is recorded. Using this process it becomes apparent which mitigation or mitigations are needed to reduce the risk to an acceptable level. The mitigation matrix (page 36) was used in the mitigation report on Siberian log imports (USDA, APHIS,

1991) which addresses the exotic pest organisms identified in the Siberian log risk assessment (USDA, FS, 1991).

STEP 4: Developing a realistic operational approach is not easy. Each new operational decision must take into consideration a number of management, agency, and biological factors that will always be unique to any specific organism or pathway. However, at an operational risk management level each one of the steps in the operational pyramid (page 37) is a process that needs to be examined before approval of the importation, or release, or action against, an exotic organism or pathway is taken. These include the risk assessment, the development of conditions for entry to meet current regulatory requirements, effective mitigation of pests in the risk assessment if any are identified, feasibility of the importers to meet the requirements, and finally, a system of monitoring to ensure that all regulatory requirements are maintained.

Summary Table—Mitigation measures available for pests and pathogens associated with larch timber from the Soviet Union

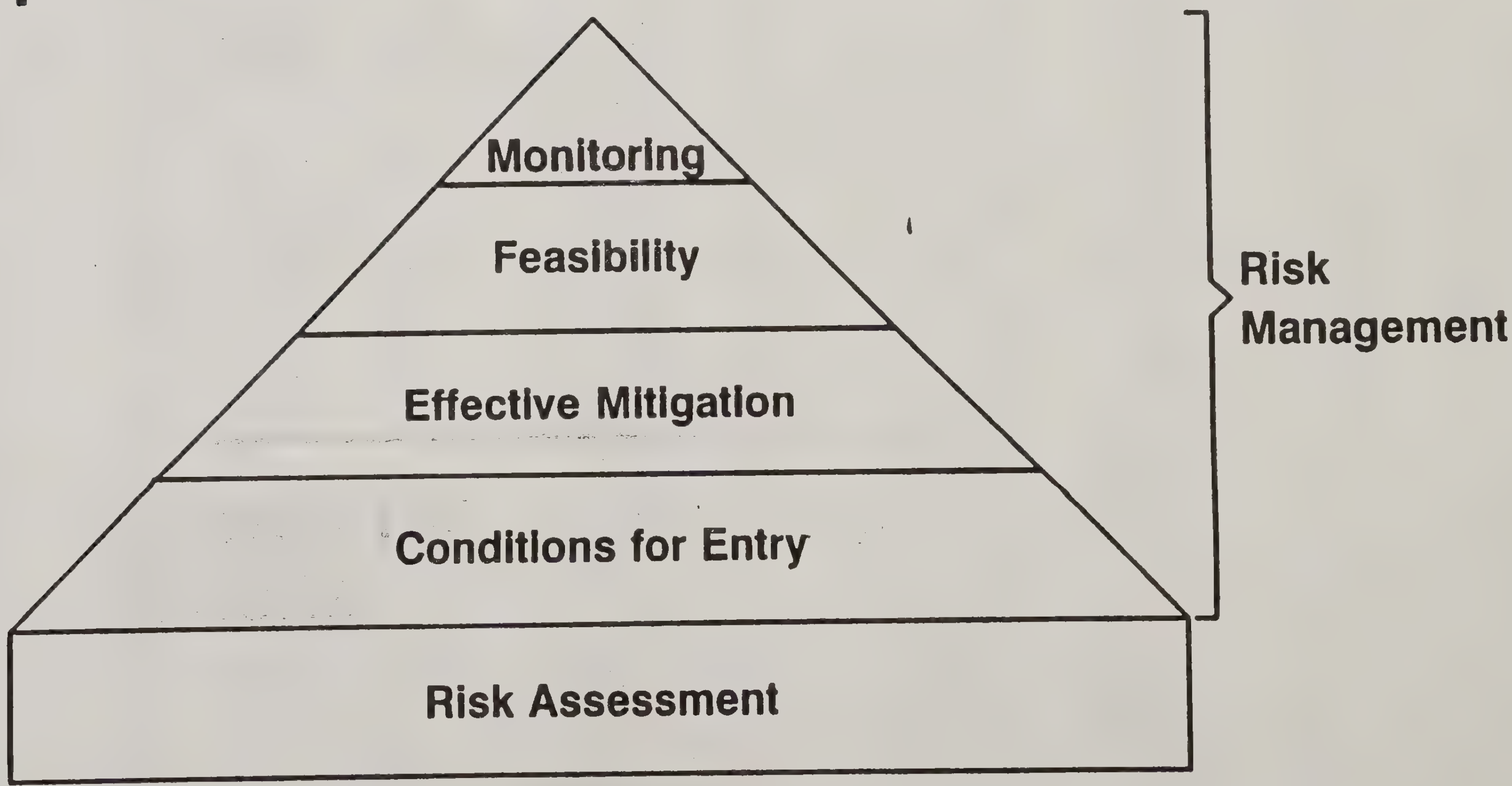
	MB	SF	PH	KD	SH	IR	DB
Pests on the outer surface							
Asian gypsy moth (*Lymantria dispar*) Nun moth (*Lymantria monacha*)	E	N	E	E	E	R	E
Root/stump insects (Scolytidae, Curculionidae) *Hylastes, Hylurgus, Hylobius, Hylurgops*	E	E	E	E	E	E	E
Scale insects (*Physokermes, Aspidiotus, Lepidosaphes, Nuculaspis, Matsucoccus*)	E	E	E	E	E	R	E
Flatbugs (*Aradus cinnamomeus*)	E	E	E	E	E	R	E
Aphids (*Cinara sp.*) Wooly adelgids (*Adelges* spp.) Siberian silk moth (*Dendrolimus sibericus*)	E	E	E	E	E	R	E
Pathogens Melampsora rust (*Melampsora sp.*) Larch needle cast (*Meria laricis*) Conifer shoot blight (*Sirococcus strobilinus*)	R	N	N	E	E	R	E
Pests in or under the bark							
Engraver beetles (*Ips duplicatus, I. sexdentatus, I. subelongatus, I. typographus, Dendroctonus micans*) Weevils (*Pissodes* spp.)	E	E	E	E	E	R	E
Pests in the wood							
Monochamus urussovi, Xylotrechus altaicus	E	E	E	E	E	N	N
Siricidae (*Paururus, Xeris, Sirex*)	E	E	E	E	E	N	N
Pathogens Larch canker (*Lachnellula willcommii*) Annosus root rot (*Heterobasidion annosum*) Staining/vascular diseases (*Ophiostoma sp.*) Red ring rot (*Phellinus sp.*) *Leptographium spp.*	R	R	R	E	E	N	N
Wood nematodes (*Bursaphelenchus kolymensis, B. mucronatus*)	R	R	E	E	E	N	N

Abbreviations:
MB — Methyl bromide fumigation
SF — Sulfuryl fluoride fumigation
PH — Phosphine fumigation
***KD** — Kiln drying
SH — Steam heat or hot water dip
IR — Irradiation
DB — Debarking

E — Effective
N — Not effective
R — Requires research

***Note on kiln drying:** This treatment would be applicable to squared and cut lumber but not whole logs.

Building Systems for Safe Importations



APPENDIX D: DEFINITIONS

COMMODITY ASSESSMENT - A non-indigenous pest risk assessment associated with the foreign importation of a commodity (i.e. logs, fruit, nursery stock, etc.)

ECONOMIC IMPACT POTENTIAL - The expected net change in societies net welfare which is the sum of the producers' and consumers' surpluses arising from changes in yield and cost of production caused by the pest.

ECONOMIC THRESHOLD - The pest density at which control measures should be implemented to prevent an increasing pest population from reaching the density to cause economic damage.

ENTRY POTENTIAL - The relative ability of an organism to penetrate the borders of a given area within a time interval.

ESTABLISHED - The condition of a species that has formed a self-sustaining, free-living population at a given location (OTA, 1993).

EXOTIC - Non-indigenous

INDIGENOUS - The condition of a species being within its natural range or natural zone of potential dispersal; excludes species descended from domesticated ancestors (OTA, 1993).

INTRODUCTION - All or part of the process by which a non-indigenous species is imported to a new locale and is released or escapes into a free-living state (OTA, 1993).

NATIVE - Indigenous

NON-INDIGENOUS - The condition of a species being beyond its natural range or natural zone of potential dispersal; includes all domesticated and feral species and all hybrids except for naturally occurring crosses between indigenous species (OTA, 1993).

ORGANISM - Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, viroids, viruses, or any entity characterized as living, related to the foregoing.

PATHWAY - Any means and/or route by which a non-indigenous pest can move or be moved from one place to another.

PEST - An organism whose undesired effects outweigh its beneficial effects at it relates to a specific time or place.

RISK - Is the likelihood and magnitude of an adverse event.

RISK ANALYSIS - The process that includes both risk assessment and risk management.

RISK ASSESSMENT - The estimation of risk.

RISK COMMUNICATION - The act or process of exchanging information concerning risk.

RISK MANAGEMENT - The pragmatic decision making process concerned with what to do about the risk.

APPENDIX E: Example of Risk Assessments that used the Generic Process

I. COMMODITY ASSESSMENTS:

USDA FOREST SERVICE. 1991. Pest Risk Assessment of the Importation of Larch from Siberia and the Soviet Far East. Miscellaneous Publication No. 1495

USDA FOREST SERVICE. 1992. Pest Risk Assessment of the Importation of *Pinus radiata* and Douglas-fir Logs from New Zealand. Miscellaneous Publication No. 1508

USDA FOREST SERVICE. 1993. Pest Risk Assessment of the Importation of *Pinus radiata*, *Nothofagus dombeyi* and *Laurelia philippiana* Logs from Chile. Miscellaneous Publication No. 1517

II. SPECIFIC ORGANISM ASSESSMENT:

Huettel, R.L.; Griffin, R.L. and Caplen R.T. 1993. Pest Risk Analysis for Pea Cyst Nematode. USDA APHIS PPQ/PPD risk assessment, 15p.

Lehtonen, P. 1993. Pest Risk Assessment on Chinese Water Spinach. USDA APHIS PPQ risk assessment, 22p.

Orr, R.L. and Cohen, S. 1991b. Pest Risk Assessment on Potato Virus Y-N. APHIS PPD risk assessment, 14p.

Orr, R.L. 1991a. Pest Risk Assessment on Apple Ermine Moth. USDA APHIS PPQ risk assessment, 15p.

Orr, R.L. 1991b. Pest Risk Assessment on Cherry Bark Tortrix. USDA APHIS PPQ risk assessment, 13p.

Schall, R.A. 1991. Pest Risk Assessment on Karnal Bunt. USDA APHIS PO risk assessment, 14p.

Schall, R.A. 1992. Pest Risk Assessment on Larch-Poplar Rust. USDA APHIS PO risk assessment, 17p.

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